

**REMARKS**

This Response, filed in reply to the Office Action dated November 30, 2007, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 13-15 are all the claims pending in the application. Claims 13-15 are rejected. Claims 13 and 14 are amended. Support for the amendments to Claims 13 and 14 can be found throughout the specification, and at least at, for example, paragraphs [0037] and [0043] of the specification as published. No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

***Drawings***

Applicants thank the Examiner for acknowledging acceptance of the drawings submitted on September 11, 2007.

***Claim to Priority***

Applicants thank the Examiner for acknowledging Applicants' claim to priority and receipt of the priority documents.

***Withdrawn Objections/Rejections***

Applicants thank the Examiner for withdrawal of the objection to Figure 6A and the objection to the specification.

Further, Applicants thank the Examiner for withdrawal of the rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a), and for withdrawal of the double patenting rejection over copending U.S. Application No. 10/939,468, as set forth in the Office Action mailed June 11, 2007.

***Claim 13 is Patentable Under 35 U.S.C. § 102***

On page 3 of the Office Action, Claim 13 is rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Hayes *et al.* (*Journal of Clinical Pathology*, 1999, 52:97-103), as evidenced by Kondo *et al.* (U.S. Patent No. 5,853,981, issued December 29, 1998).

It is alleged that Hayes *et al.* disclose a method comprising obtaining RNA transcripts from human individuals infected with Epstein-Barr virus (EBV). The Office asserts that with regard to step (A) of instant Claim 13, the “selected DNA molecule” is the EBV genomic sequence.

With regard to step (B) of instant Claim 13, the Office asserts that Hayes *et al.* disclose the screening of selected portions of the EBV genomic sequence, namely those regions encoding the vIL-10, BDLF2 and BARF1 proteins. The Office asserts that the nucleotide sequence of each of these regions is known, and the purpose of the study by Hayes *et al.* was to determine which regions were expressed in different types of EBV infection.

With regard to Step (B)(i) of instant Claim 13, the Office asserts that Hayes *et al.* disclose that the obtained RNA transcripts were amplified with first and second primers. Further, the Office refers to Table 3 of Hayes *et al.* to assert that for the amplification of the region encoding vIL-10, the first primer was complementary to 19 continuous nucleotides located at or near the 3' end of the selected portion of the selected DNA molecule, and the second primer was complementary to 23 continuous nucleotides located at or near the 5'-end of the selected portion of the selected DNA molecule.

With regard to steps (B)(i)(a)-(B)(i)(c), the Office admits that Hayes *et al.* do not specifically recite each step of NASBA amplification. In this regard, the Office refers to Kondo

*et al.* to make the point that steps (B)(i)(a)-(B)(i)(e) of instant Claim 13 are an inherent property of the NASBA method performed by Hayes *et al.*

Further, with regard to step (B)(ii) of instant Claim 13, the Office alleges that Hayes *et al.* disclose that the amplification products were detected in order to screen for an RNA transcript that is encoded by the selected portion of the selected DNA molecule.

Further still, regarding step (C) of instant Claim 13, the Office alleges that Hayes *et al.* disclose a method for screening at least 3 selected portions of the EBV DNA genome. The Office asserts that each portion (i.e., vIL-10, BDLF2, and BARF1) is different from, and nonoverlapping with the other portions, as evidenced by Table 3 of Hayes *et al.*

Solely to advance prosecution, and to even further clarify Applicants' claimed invention, Applicants herewith amend Claim 13 to recite that the at least one selected portion of the selected DNA molecule is also adjacent to the selected portion of (B). Support for this recitation is implicitly and inherently disclosed in Example 1 of the instant specification, and in Figure 1. Applicants respectfully submit that neither Hayes *et al.* nor Kondo *et al.* disclose step (C) of Claim 13 as amended. Rather, Kondo *et al.* only disclose amplification of one portion, that is, the  $\beta$ 2.7 gene of cytomegalovirus. As shown in Table 3 by the nucleotide coordinates of the vIL-10, BDLF2 and BARF1 genes in the EBV genome, Hayes *et al.* do not disclose the amplification of adjacent DNA portions. Thus, Hayes *et al.*, as evidenced by Kondo *et al.*, fail to teach each and every element of the claims, as is required to maintain a rejection under 35 U.S.C. 102(b).

**Withdrawal of rejection is therefore respectfully requested.**

***Claims 14 and 15 are Patentable Under 35 U.S.C. § 103***

On page 6 of the Office Action, Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes *et al.* (*Journal of Clinical Pathology*, 1999, 52:97-103), as evidenced by Kondo *et al.* (U.S. Patent No. 5,853,981, issued December 29, 1998) as applied to the rejection of Claim 13, mentioned above, and further in view of Ishiguro *et al.* (*Nucleic Acids Research*, 1996, vol. 24, No. 24).

The Office asserts that the teachings of Hayes *et al.*, as evidenced by Kondo *et al.*, are presented under the rejection of Claim 13 under 35 U.S.C. 102(b).

With regard to the rejection of Claims 14 and 15 further in view of Ishiguro *et al.*, the Office alleges that Hayes *et al.*, as evidenced by Kondo *et al.*, do not disclose that the probe is labeled with an intercalating fluorescent dye. Further, the Office admits that Hayes *et al.*, as evidenced by Kondo *et al.*, do not disclose an intercalating fluorescent dye that has a differential fluorescence characteristic depending on whether said probe exists in an unbound single-stranded state or in a bound duplex with said amplification product.

In an attempt to rectify this deficiency, the Office cites Ishiguro *et al.*, who allegedly disclose a fluorescent intercalative dye-labeled probe which can recognize a specific nucleic acid sequence by linking of a fluorescent intercalative dye as a label to a single-stranded oligonucleotide that is complementary in sequence to a specific nucleic acid sequence. Upon hybridization, the intercalative dye intercalates into the resulting double-stranded oligonucleotide to alter the fluorescent property.

From these references, the Office asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hayes *et al.* by using probes linked to fluorescent intercalative dyes as suggested by Ishiguro *et al.*

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

To establish a *prima facie* case of obviousness, three criteria must be established. First, the references must, in combination, teach each and every limitation of the currently claimed invention, *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974). Second, the Office must provide sufficient reason why one of skill in the art would combine the references to arrive at the claimed invention. Finally, there must be a reasonable expectation of success in combining the references. Applicants respectfully submit that the cited references fail to render the instant claims *prima facie* obvious. As mentioned under the 35 U.S.C. § 102(b) claim rejection, Hayes *et al.*, as evidenced by Kondo *et al.*, do not teach each and every element of the claimed invention. The addition of Ishiguro *et al.* does not compensate for the deficiencies of the primary references since Ishiguro *et al.* only disclose the use of a fluorescently-labeled oligonucleotide. Thus, the cited references, taken alone or in combination, do not teach each and every element of the claims, as is required to maintain a rejection under 35 U.S.C. § 103. Accordingly, one of ordinary skill in the art would not have a reasonable expectation of success of arriving at the claimed invention by combining these three references. Thus, the claimed invention is not rendered obvious by the cited references.

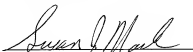
**Withdrawal of the rejection is therefore respectfully requested.**

***Conclusion***

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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